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**Assessment of genetically modified maize MON 88017 for renewal
authorisation under Regulation (EC) No 1829/2003 (application
EFSA-GMO-RX-014)**

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; Veronesi, Fabio ; Álvarez, Fernando ; Ardizzone, Michele ; Raffaello, Tommaso

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Assessment of genetically modified maize MON 88017 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-014)

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Abstract

Following the submission of application EFSA-GMO-RX-014 under Regulation (EC) No 1829/2003 from Monsanto Company the Panel on Genetically Modified Organisms of the European Food Safety Authority was asked to deliver a scientific risk assessment on the data submitted in the context of the renewal of authorisation application for the insect-resistant and herbicide-tolerant genetically modified maize MON 88017, for food and feed uses, excluding cultivation within the EU. The data received in the context of this renewal application contained post-market environmental monitoring reports, a systematic search and evaluation of literature, updated bioinformatic analyses, and additional documents or studies performed by or on behalf of the applicant. The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application. Under the assumption that the DNA sequence of the event in maize MON 88017 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-014 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 88017.

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Keywords: Maize, MON 88017, renewal, Articles 11 and 23, Regulation (EC) No 1829/2003

Requestor: European Commission (DG SANTE)

Question number: EFSA-Q-2018-00672

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Summary

Following the submission of application EFSA-GMO-RX-014 under Regulation (EC) No 1829/2003 from Monsanto Company, the Panel on Genetically Modified Organisms of the European Food Safety Authority (GMO Panel) was asked to deliver a scientific risk assessment on the data submitted in the context of the renewal of authorisation application for the insect-resistant and herbicide tolerant genetically modified maize MON 88017. The scope of the renewal application EFSA-GMO-RX-014 is for the renewal of the placing on the market of products containing, consisting of, or produced from maize MON 88017, excluding cultivation within the European Union (EU).

In delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-RX-014, additional information provided by the applicant, scientific comments submitted by the EU Member States and relevant scientific publications. The data received in the context of the renewal application EFSA-GMO-RX-014 contained: post-market environmental monitoring reports, an evaluation of the literature retrieved by a systematic search, updated bioinformatics analyses, and additional studies performed by or on behalf of the applicant. The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application.

Under the assumption that the DNA sequence of the event in maize MON 88017 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in the renewal application EFSA-GMO-RX-014 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 88017 (EFSA, 2009).

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1. Introduction

1.1. Background

On 29 August 2018, the European Food Safety Authority (EFSA) received from the European Commission (EC) application EFSA-GMO-RX-014 for the renewal of the authorisation of maize MON 88017 (Unique Identifier MON-88Ø17-3), submitted by Monsanto (hereafter referred to as 'the applicant') according to Regulation (EC) No 1829/2003.¹

Following receipt of application EFSA-GMO-RX-014, EFSA informed the Member States (MS) and made the summary of the application available to the public on the EFSA website.²

EFSA checked the application for compliance with the relevant requirements of Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013³ and, when needed, asked the applicant to supplement the initial application. On 17 December 2018, EFSA declared the application valid and made the valid application available to the MS and the EC.

Following the submission of application EFSA-GMO-CZ-2005-27 and the publication of the EFSA scientific opinion (EFSA, 2009), the placing on the market of maize MON 88017 for products containing, consisting of, or produced from this GM maize, excluding cultivation in the EU, was authorised by Commission Decision 2009/814/EC.⁴ A copy of this authorisation was provided by the applicant.⁵

From the validity date, EFSA and its scientific Panel on Genetically Modified Organisms (hereafter referred to as 'the GMO Panel') endeavoured to respect a time limit of 6 months to issue a scientific opinion on application EFSA-GMO-RX-014. Such time limit was extended whenever EFSA and/or its GMO Panel requested supplementary information to the applicant. According to Regulation (EC) No 1829/2003, any supplementary information provided by the applicant during the risk assessment was made available to the MS and European Commission (for further details, see the section 'Documentation', below).

In accordance with Regulation (EC) No 1829/2003, EFSA consulted the nominated risk assessment bodies of the MS, including national Competent Authorities within the meaning of Directive 2001/18/EC.⁶ The MS had three months to make their opinion known on application EFSA-GMO-RX-014 as of date of validity.

1.2. Terms of Reference as provided by the requestor

According to Articles 6 and 18 of Regulation (EC) No 1829/2003, EFSA and its GMO Panel were requested to carry out a scientific risk assessment of maize MON 88017 for the renewal of authorisation for placing on the market of products containing, consisting of, or produced from GM maize MON 88017 in the context of its scope as defined in application EFSA-GMO-RX-014.

According to Regulation (EC) No 1829/2003, this scientific opinion is to be seen as the report requested under Articles 6(6) and 18(6) of that Regulation including the opinions of the nominated risk assessment bodies of the MS.⁷

In addition to the present scientific opinion on maize MON 88017, EFSA and its GMO Panel were also asked to report on the particulars listed under Articles 6(5) and 18(5) of Regulation (EC) No 1829/2003. The relevant information is made available in the EFSA Register of Questions,⁸ including the information required under Annex II to the Cartagena Protocol, a labelling proposal, a post-market environmental monitoring (PMEM) plan as provided by the applicant; the method(s), validated by the Community reference laboratory, for detection, including sampling, identification of the transformation event in the food-feed and/or foods-feeds produced from it and the appropriate reference materials.

¹ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 18.10.2003, p. 1–23.

² Available online: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionDocumentsLoader?question=EFSA-Q-2018-00672>

³ Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006. OJ L157, 8.6.2013, p. 1–48.

⁴ Commission Decision of 30 October 2009 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 88017 (MON-88Ø17-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union L 289/25, 5.11.2009.

⁵ Dossier: Maize MON 88017 – Annex 1.

⁶ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. OJ L 106, 12.3.2001, p. 1–38.

⁷ Opinions of the nominated risk assessment bodies of EU Member States can be found at the EFSA Register of Questions,

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionDocumentsLoader?question=EFSA-Q-2018-00672>

2. Data and methodologies

2.1. Data

The data for application EFSA-GMO-RX-014 provided by the applicant at the time of submission, or in reply to requests for additional information, are specified below.

In the context of this renewal application, no new sequencing study was submitted among the additional documents or studies performed by or on behalf of the applicant. In accordance with the GMO Panel guidelines for renewal of applications of GM food and feed authorised under Regulation (EC) No 1829/2003 (EFSA GMO Panel, 2015), the GMO Panel evaluated the data provided in the context of this maize MON 88017 renewal application under the assumption that the MON 88017 event sequence is identical to the sequence of the originally assessed event (EFSA, 2009).

2.1.1. Post-market monitoring reports⁹

Based on the outcome of the initial food and feed risk assessment, a post-market monitoring plan for monitoring of GM food and feed was not required by the authorisation decision. The implementation of a PMEM plan, consisting of a general surveillance plan to check for any adverse effects on the environment arising from maize MON 88017, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment of maize MON 88017 (EFSA, 2009), case-specific monitoring was not considered necessary by the GMO Panel.

The applicant provided ten annual PMEM reports covering a reporting period from July 2009 till June 2019. The annual PMEM plans submitted by the applicant included (1) commodity crop (GM and non GM) imports into the EU by country of origin and destination; (2) the description of a centralised system established by EuropaBio for the collection of information recorded by various operators (federations involved in maize grains import and processing) on any observed adverse effect(s) on human health and the environment arising from handling of maize possibly containing maize MON 88017; (3) the reports of the surveillance activities conducted by such operators; and (4) the review of relevant scientific peer-reviewed studies retrieved from literature searches.

2.1.2. Systematic search and evaluation of literature¹⁰

In addition to the separate searches provided as part of the annual PMEM reports, the applicant performed two systematic literature searches covering the period from January 2008 till September 2019, in accordance with the recommendations on literature search outlined in EFSA (2010, 2017a).

Searches in electronic bibliographic databases and in websites of relevant organisations were performed to identify relevant publications. Altogether, 607 publications were identified (after removal of duplicates). After applying the eligibility/inclusion criteria defined a priori by the applicant, eleven publications were identified as relevant for food and feed safety assessment or molecular characterisation. The list of relevant publications is provided in Appendix A.

2.1.3. Updated bioinformatic data¹¹

At the time of submission of the renewal dossier, the applicant provided a complete bioinformatic dataset for maize MON 88017 event including an analysis of the insert and flanking sequences, an analysis of the potential similarity to allergens and toxins of the newly expressed proteins and of all possible open reading frames (ORFs) within the insert and spanning the junction sites, an analysis of possible horizontal gene transfer (EFSA, 2017b), and a safety assessment of the newly expressed proteins Cry3Bb1 and CP4 EPSPS regarding their capacity to trigger celiac disease (EFSA GMO Panel, 2017a). Upon EFSA request, the applicant provided additional information followed by further clarifications on the celiac disease analysis for Cry3Bb1 protein. The outcome of the updated bioinformatic analyses is presented in Section 3.3.

⁹ Dossier: Maize MON 88017 – Annex 2; additional information 21/12/2018 and 21/1/2020.

¹⁰ Dossier: Maize MON 88017 – Annex 3.1; additional information: 8/4/2019 and 2/12/2019.

¹¹ Dossier: Maize MON 88017 – Annex 3.2; additional information: 30/9/2019.

2.1.4. Additional documents or studies provided by the applicant¹²

In line with the renewal guidance requirements (EFSA GMO Panel, 2015), the applicant provided an overview on the worldwide approvals of maize MON 88017 and searched for any available full reports of studies performed by or on behalf of the applicant over the course of the authorisation period and not previously submitted to the EU.

2.1.5. Overall assessment as provided by the applicant¹³

The applicant provided an overall assessment concluding that information provided in the application for renewal of authorisation of maize MON 88017 for food and feed uses in the EU does not change the outcome of the original risk assessment (EFSA, 2009).

2.1.6. Monitoring plan and proposal for improving the conditions of the original authorisation¹³

The applicant indicated in the dossier that the environmental post-market monitoring plan is appropriate and does not need any changes.

2.2. Methodologies

The GMO Panel assessed the application for renewal of the authorisation of maize MON 88017 for food and feed uses in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003. The GMO Panel took into account the requirements described in its guideline for the risk assessment of renewal applications of GM food and feed authorised under Regulation (EC) No 1829/2003 (EFSA GMO Panel, 2015). The comments raised by the nominated risk assessment bodies of EU Member States were taken into consideration during the scientific risk assessment.

3. Assessment

3.1. Evaluation of the post-market monitoring reports

During the general surveillance activities covering the authorisation period of maize MON 88017, no adverse effects were reported by the applicant.

3.2. Evaluation of the systematic search and evaluation of literature

The GMO Panel assessed the applicant's literature searches on maize MON 88017 and the newly expressed proteins Cry3Bb1 and CP4 EPSPS. The overall quality of the performed literature searches is acceptable; however, the GMO Panel considers that future searches could be fine-tuned. The GMO Panel therefore recommends the applicant for future searches to:

- ensure that enough search term variation is used (covering possible synonyms, related terms, acronyms, spelling variants, old and new terminology, brand and generic names, lay and scientific terminology, common typos, translation issues);
- adapt the search to the size of the retrieved publications (and thus not combine search sets when one of the search sets already yields only a small number of publications).

The GMO Panel acknowledges that no publications raising a safety concern for human and animal health and the environment which would change the original risk assessment conclusions on maize MON 88017 (EFSA, 2009) have been identified by the applicant.

3.3. Evaluation of the updated bioinformatic data

The results of the updated bioinformatic analyses of maize MON 88017 confirm previous analyses indicating the partial deletion of an endogenous gene. Based on the information from the updated databases submitted in the frame of this renewal application, this gene is identified as putative purine permease 11. There are eight predicted purine permease loci with multiple coding sequences annotated in the maize reference genome, thereby indicating a possible functional redundancy for this

¹² Dossier: Maize MON 88017 – Annex 3.3

¹³ Dossier: Maize MON 88017 – Annex 4.

gene. In addition, the original agronomic, phenotypic and compositional analyses of maize MON 88017 did not indicate relevant differences as compared to the non-GM comparator (EFSA, 2009).

Analyses of the amino acid sequence of the newly expressed Cry3Bb1 and CP4 EPSPS proteins reveal no significant similarities to toxins, allergens or immunogenic gluten-related epitopes. In addition, bioinformatic analyses of the newly created ORFs within the insert or spanning the junctions with genomic DNA confirm the previous conclusions indicating that the expression of ORFs showing significant similarities to toxins or allergens for the event MON 88017 is highly unlikely (EFSA GMO Panel, 2017b, 2019).

The updated bioinformatic analysis for maize event MON 88017 confirms previous conclusions which did not reveal any DNA sequence that could provide sufficient length and identity which could facilitate horizontal gene transfer (HGT) by double homologous recombination confirming previous conclusions (EFSA GMO Panel, 2017b, 2019). Given the results of this analysis and that the recombinant DNA in maize MON 88017 does not confer selective advantages to microorganisms, the GMO Panel identified no safety concern linked to an unlikely but theoretically possible HGT.

3.4. Evaluation of the additional documents or studies provided by the applicant

Taking into account (i) the relevance for molecular characterisation, human and animal safety and the environment; and (ii) the scope of this renewal application, there are no unpublished studies available performed by the applicant and not previously submitted to the EU since MON 88017 was authorised.

3.5. Evaluation of the overall assessment as provided by the applicant

The GMO Panel evaluated the overall assessment provided by the applicant and confirms that there is no evidence in renewal application EFSA-GMO-RX-014 indicating new hazards, relevant changes in exposure or scientific uncertainties that would change previous conclusions on maize MON 88017.

3.6. Evaluation of the monitoring plan and proposal for improving the conditions of the original authorisation

The PMEM plan covers general surveillance of imported GM plant material, including maize MON 88017. This general surveillance is coordinated by EuropaBio and implemented by selected operators (federations involved in maize grains import and processing). In addition, the applicant reviews relevant scientific publications retrieved from literature searches on an annual basis. The GMO Panel is of the opinion that the scope of the plan provided by the applicant is consistent with the scope of application EFSA-GMO-RX-014, but reminds that monitoring is related to risk management, and thus the final adoption and implementation of the PMEM plan falls outside the mandate of EFSA.

4. Conclusions

Under the assumption that the DNA sequence of the event in maize MON 88017 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-014 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 88017 (EFSA, 2009).

Documentation as provided to EFSA

- 1) Letter from the European Commission to EFSA received on 29 August 2018 for the continued marketing of genetically modified maize MON 88017 submitted in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 by Monsanto Company (EFSA-GMO-RX-014).
- 2) Application EFSA-GMO-RX-014 validated by EFSA, 17 December 2018.
- 3) Request for supplementary information to the applicant, 04 February 2019.
- 4) Request for supplementary information to the applicant, 11 March 2019.
- 5) Receipt of supplementary information from the applicant, 08 April 2019.
- 6) Receipt of supplementary information from the applicant, 12 June 2019.
- 7) Request for supplementary information to the applicant, 29 July 2019.
- 8) Receipt of supplementary information from the applicant, 30 September 2019.

- 9) Request for supplementary information to the applicant, 2 October 2019.
- 10) Receipt of supplementary information from the applicant, 2 December 2019.

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- EFSA (European Food Safety Authority), Gennaro A, Gomes A, Herman L, Nogue F, Papadopoulou N and Tebbe C, 2017b. Technical report on the explanatory note on DNA sequence similarity searches in the context of the assessment of horizontal gene transfer from plants to microorganisms. EFSA supporting publication 2017: EN-1273. 11pp. <https://doi.org/10.2903/sp.efsa.2017.en-1273>
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- EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli H, Birch AN, Casacuberta J, De Schrijver A, Gralak MA, Guerche P, Jones H, Manachini B, Messéan A, Nielsen EE, Nogué F, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Wal J-M, Álvarez F, Lanzoni A and Paraskevopoulos K, 2017b. Scientific Opinion on application EFSA-GMO-BE-2013-118 for authorisation of genetically modified maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 and subcombinations independently of their origin, for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto Company. EFSA Journal 2017;15(8):4921, 32 pp. <https://doi.org/10.2903/j.efsa.2017.4921>
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Abbreviations

GM	genetically modified
GMO	genetically modified organism
GMO Panel	EFSA Panel on Genetically Modified Organisms
HGT	horizontal gene transfer
ORFs	open reading frames
PMEM	post-market environmental monitoring

Appendix A – List of relevant publications identified by the applicant through systematic literature searches (January 2008–September 2019)

Reference

- Bakó A, Gell G, Zámbo Á, Spitkó T, Pók I, Pintér J and Balázs E, 2013. Monitoring transgene expression levels in different genotypes of field grown maize (*Zea mays* L.). *South African Journal of Botany*, 84, 6–10.
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†: Publication identified in the literature search performed for the 2019 post-market environmental monitoring report.